



**This is in response to the letter on September 25, 2003**

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**OFFICE OF PETITIONS**

## **Trach Sensory ALERT System**

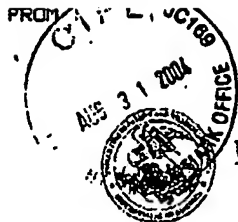
The Trach Sensory Alert system is designed to alarm when the trach starts to move out of the body. The temperature setting can be changed for each individual according to their body temperature. The unit is one unit with the sensor at the curve of the trach [on the back of the trach],[not like the unit in the Harris Patent #3,903,876, and the Einhorn Patent # 5,070,321 which both have two parts to the trach an inner cannula and an outer cannula]. There is no balloon on the trach and no inner cannula on the trach. The balloon on a trach can get skin growing around the balloon [adhere] on the inside of the body [outside of trach]. Trach's are usually changed on a monthly bases.

The Trach Sensory Alert System is for both occlusions and for when the trach starts coming out of the body.

The differences are my unit is one piece not two pieces and I don't have an inner cannula.

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[850-562-4123]



FAX NO. :

Aug. 30 2004 02:05PM P2/S

10/035,472

DAC  
JFW

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
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Alexandria, Virginia 22313-1100  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	EXAMINATION NO.
10/035,472	10/23/2001	Loretta S. Brodeur	00-08377	4020

7590 09/25/2003  
Joseph N. Breaux  
Suite A  
10630 N. Oak Hills Pkwy.  
Baton Rouge, LA 70810

EXAMINER

MCCROSKY, DAVID J

ANT UNIT PAPER NUMBER

3736

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Notice of References Cited**

Application/Control No.

10/035,472

Applicant(s)/Patent Under  
Reexamination  
BROSHEARS, LORETTA S.

Examiner

David J. McCrosky

Art Unit

3736

Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-3,803,878	09-1975	Harris, Thomas R.	600/537
	B	US-5,070,321	12-1991	Elmhorn et al.	600/537
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

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\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office  
PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 2

May 17 2004 12:26PM P2/4

FRX NO. :

FROM :



850 562-2895

Application No. 10/035,472	Applicant(s) BROSHEARS, LORETTA S.	
Examiner David J. McGrosky	Art Unit 3738	

## Office Action Summary

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

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## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Einhorn et al in view of Harris. Einhorn et al teach a temperature sensor (20) within a tracheotomy tube. The temperature sensor (20) is coupled to an alarm system (18). An audio visual alarm (44) is sounded due to dislodging or cessation of breathing patterns. See col. 3, ll. 34-43. While disclosing an alarm system that is triggered when predetermined criteria is met (no change in air temperature over a preset time interval), Einhorn et al do not specifically recite setting a predetermined temperature. However, Harris discloses a tracheotomy tube with a temperature sensor (thermistor). See col. 3, ll. 3-9. When air movement stops, the temperature changes such that a critical threshold (predetermined temperature) is reached and an alarm sounds. The advantage is to provide a warning before breathing or movement of the patient has ceased altogether. See col. 2, ll. 51-61. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the alarm system of Einhorn et al with the predetermined temperature setting of Harris to provide a warning before breathing or movement of the patient has ceased altogether.

***Conclusion***

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Art Unit: 3736

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. McCrosky whose telephone number is 703-305-1331. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DJM

  
MAX F. HINDENBURG  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

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